

REMARKS

At the outset, the attorney of record wishes to thank Examiner Sorbello for her time and assistance in the prosecution of the present application, most notably the telephonic communications on January 2, 4 and 8th of this year.

Status of the claims

Claims 10-19 are presently under consideration. In the instant amendment, claims 12, 13, 15, 17, and 18 are amended; and claim 20 is added. Support for the amendment to claim 12 drawn to an isolated mouse strain from BALB/c mice homozygous for developing rheumatoid arthritis can be found, *inter alia*, on page 6, lines 3-7. Claim 13 has been amended to place it in independent form. Both claims 13 and 18 have also been amended to clarify the scope of the claims as suggested by the Examiner. Support for new claim 20 directed to a mouse homozygous for the trait of developing rheumatoid arthritis by six months of age can be found, *inter alia*, in Examples 2-7 and, in particular, at page 6, lines 22-23, of the specification. The Examples compare mice of the invention (between 5 to 6 months of age) to normal BALB/c mice (between 5 to 6 months of age). No new matter has been introduced by the claim amendments.

Allowable claims

Applicant thanks the Examiner for finding that claims 13 and 18 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

Outstanding rejections

The rejection of claims 12 and 14 are rejected under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter has been maintained. The rejection of claims 10-12, 14-17, and 19 are rejected under 35 U.S.C. §112, first paragraph, for allegedly not providing enabling disclosure has been maintained. Claims 10-12 and 14 are rejected under 35 U.S.C.

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§102(e) for allegedly being anticipated by U.S. Patent No. 4,950,741 to Yamanaka *et al.* (hereinafter "Yamanaka"). Applicants respectfully traverse all outstanding objections to the specification and rejections of the claims.

Claim objections

Claims 10, 11, and 14 have been objected to for depending on rejected claim 12. Applicant submits that amended claim 12 is allowable for the reasons set forth below. Accordingly, Applicant respectfully requests withdrawal of this objection.

Claims 13 and 18 are objected to as they recite a deposit of a mouse and a mouse strain, respectively, with the ATCC. Applicant has amended the claims as suggested by the Examiner to overcome this objection.

Claims 13 and 18 are objected to for allegedly being dependent upon a rejected base claim. Applicant respectfully submits that the base claim is allowable for reasons set forth herein. However, Applicant has amended claim 13 to be in independent form.

Issues under 35 U.S.C. §101

The rejection of claims 12 and 14 under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter has been maintained.

The Patent Office, on page 3 of the Office Action, alleges that claim 12 still reads on a product of nature because a distinction from a naturally occurring BALB/c mouse has not been claimed. The Patent Office further alleges that Applicant has not stipulated any characteristic or limited the claim in any way so that one can be assured that this strain has the characteristic claimed.

Applicant has amended claim 12 to recite that the claimed mouse is homozygous for the trait of developing rheumatoid arthritis. That the mouse is homozygous for this trait distinguishes the claimed mouse from those found in nature. Evidence that the mouse is

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homozygous for this trait is provided in the attached Declaration by Dr. Sakaguchi. Based on his experiments, the results of which are presented in the Declaration, Dr. Sakaguchi states that the claimed mouse strain is homozygous, see paragraphs 8 and 9 of the Declaration. The experiments also highlight the phenotypic differences between the claimed mouse strain and the parent BALB/c mouse strain.

Accordingly, the mice of the claimed mouse strain possess a characteristic not found in normal BALB/c mice. In light of the amendment and reasons provided, Applicant respectfully requests that the rejection of claims 12 and 14 under 35 U.S.C. §101 for allegedly being directed to non-statutory subject matter be withdrawn.

Issues under 35 U.S.C. §112, first paragraph

The rejection of claims 10-12, 14-17, and 19 under 35 U.S.C. §112, first paragraph, for allegedly not providing enabling disclosure has been maintained. The Patent Office alleges that the specification, while being enabling for a mouse strain SKG from BALB/c mouse, a method for identifying a therapy that decreases symptoms of rheumatoid arthritis, and a method of producing offspring of a mouse strain SKG, does not reasonably provide enablement for any of the above using any BALB/c mouse.

Applicant respectfully submits that the claims are not directed to any BALB/c mouse. Amended claim 12 is directed to a mouse strain that is homozygous for the trait of developing rheumatoid arthritis. One of ordinary skill in the art, based upon his or her own knowledge and also by what is taught in the specification, would be able to distinguish mice of the invention from normal BALB/c mice. The claimed mouse strain is directed to mice that develop the disease rheumatoid arthritis and not to a particular symptom of the disease. To thus limit the claims would be to deny Applicant the full scope of patent protection to which he is entitled. Applicant respectfully submits that a skilled artisan would be able to distinguish between the claimed mice and normal BALB/c mice. Accordingly, Applicant submits that the claims are fully enabled and respectfully requests withdrawal of the rejection.

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Issues under 35 U.S.C. §102

Claims 10-12 and 14 are rejected under 35 U.S.C. §102(e) for allegedly being anticipated by U.S. Patent No. 4,950,741 to Yamanaka *et al.* (hereinafter "Yamanaka"). Applicant respectfully traverses this rejection.

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention.

The Patent Office states that Yamanaka teaches a BALB/c mouse having a trait of developing rheumatoid arthritis, citing column 2, lines 22-25, column 17, lines 66-67, and column 18, lines 1-10 of the reference.

Applicant respectfully submits that Yamanaka does not teach a BALB/c mouse having a trait of developing rheumatoid arthritis. Yamanaka discloses a purified rheumatoid arthritis specific protein ("RASP") found in patients suffering from rheumatoid arthritis and anti-RASP antibodies. Yamanaka does not teach a BALB/c mouse having the trait of developing rheumatoid arthritis. Applicant respectfully submits that although mention is made of a BALB/c mouse in column 18, lines 1-10; however, it is only in the context of immunizing the mouse to obtain antibodies. Thus, Applicant submits that Yamanaka does not teach each and every limitation of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection based upon 35 U.S.C. §102.

CONCLUSION

Claims 10-19 are pending in the application. Claims 12, 13, 15, 17, and 18 have been amended; and claim 20 has been added by the present Response. Applicant requests that the Examiner reconsider the application and claims in light of the foregoing reasons and amendments and respectfully submits that the claims are in condition for allowance.

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If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. No fees are believed to be due; however, please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

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Mi K. Kim
Mi K. Kim
Reg. No. 44,830

Fish & Richardson P.C.
PTO Customer No. 20985
4350 La Jolla Village Drive, Suite 500
San Diego, California 92122
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Version with markings to show changes made

In the claims:

Claims 12, 13, 15, 17, and 18 have been amended as follows:

12. (Amended) An isolated mouse strain from BALB/C mice[, comprising] homozygous for a trait of developing natural onset of rheumatoid arthritis.

13. (Amended) A mouse from a mouse strain capable of developing rheumatoid arthritis, wherein an embryo of the mouse strain is deposited as [which belongs to the isolated mouse strain of claim 12, and has] ATCC accession No. FERM BP-7790.

15. (Amended) A method of producing offspring of an isolated mouse strain from BALB/C mice, wherein the isolated mouse strain is homozygous for [comprises] a trait of developing [natural onset of] rheumatoid arthritis, the method comprising the steps of:

- (a) mating between mice of the isolated mouse strain in a maintained colony repeatedly to produce offspring;
- (b) screening the offspring for the trait of developing natural onset of rheumatoid arthritis.

17. (Amended) A method for producing a mouse strain from BALB/C mice being homozygous for [comprising] a trait of developing [natural onset of] rheumatoid arthritis, comprising the steps of:

- a) repeated mating between BALB/C mice in a closed colony to produce offspring; and
- b) screening the offspring for the trait of developing natural onset of rheumatoid arthritis.

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18. (Amended) The method of claim 17, wherein the mouse strain is the mouse strain from an embryo deposited as ATCC accession No. BP-7790.